UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

MICHAEL POSTAWKO, *et al*., Plaintiffs, v. MISSOURI DEPARTMENT OF CORRECTIONS, *et al*., Defendants.	)	Case No. 2:16-cv-04219-NKL

DEFENDANTS' SUGGESTIONS IN OPPOSITION TO
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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Defendants Missouri Department of Corrections ("MDOC"), Anne L. Precythe ("Precythe"), and Corizon, LLC ("Corizon," and, collectively with MDOC and Precythe, the "State") oppose Plaintiffs' Motion for a Preliminary Injunction ("Motion") because it would require this Court to substitute its judgment about treating inmates with the hepatitis C virus ("HCV") for that of the correction system's medical professionals.[1] Plaintiffs' Motion seeks to upend the Eighth Amendment standard imposed upon individuals working in a prison setting. Moreover, Plaintiffs' Motion does not seek merely to preserve the *status quo* pending a final merits determination. Instead, Plaintiffs' Motion seeks to radically alter the *status quo* with what would effectively be permanent relief. The Court should deny Plaintiffs' Motion for at least the following reasons:

(1) Plaintiffs cannot establish, on a classwide basis, a serious medical need for immediate therapy with direct acting antiviral ("DAA") drugs;

(2) Plaintiffs cannot establish a current, ongoing constitutional violation;

(3) The Ex parte Young exception to Eleventh Amendment immunity does not apply to Plaintiffs' claims because the State lacks the authority to provide the relief Plaintiffs request;

(4) Plaintiffs cannot show class-wide immediate and irreparable harm;

(5) Plaintiffs' proposed relief violates the "needs-narrowness-intrusiveness standard" under the Prison Litigation Reform Act (the "PLRA");

(6) The balance of hardships favors the State, given the substantial (and likely unrecoverable) costs the State would incur if the Court issues the preliminary injunction; and

[1] In a preliminary injunction, Plaintiffs bear the burden of proof to establish (1) a likelihood of success on the merits; (2) an immediate and irreparable harm if the injunction is not granted; (3) a threatened harm to any Plaintiff that outweighs any harm that an injunction may cause the State; and (4) the proposed injunction serves the public interest. Dataphase Sys., Inc. v. C L Sys., Inc., 640 F.2d 109, 113-14 (8th Cir. 1981) (en banc).

(7) Plaintiffs cannot show that an injunction serves the public interest.

For these reasons, as well as the evidence to be presented at the injunction hearing, Plaintiffs cannot meet the standard for a preliminary injunction, and their Motion should be denied.

STATEMENT OF FACTS

I. HCV.

HCV is a viral, blood-borne infectious disease. (Affidavit of Dr. Thomas Bredeman, dated February 28, 2017 ("Bredeman Aff.") (Doc. No. 290-2) at ¶ 4). Acute HCV infection occurs within the first six (6) months of virus exposure, while chronic HCV refers to a long-term infection. (Declaration of Dr. Jerry Lovelace, dated August 5, 2019 ("Lovelace Decl."), attached hereto as Exhibit 1, at ¶ 5). Approximately 15% to 25% of initially infected individuals "clear the virus," meaning that an individual's immune system eliminates the infection on its own without need for any additional medication or treatment. (Bredeman Aff. at ¶ 5). Current medical literature reports that 50% to 80% of HCV infected individuals develop chronic infections. (Id. at ¶ 6). That said, the majority who develop chronic HCV will never develop liver damage, and their illness will not grow more severe such that risk of complications can occur. (Id.). HCV progression to fibrosis and cirrhosis often develops over years and even decades—or, in many cases, does not occur at all. (Id.). Most HCV complications occur in people with cirrhosis. (Id.).[2]

[2] The term "cirrhosis" describes the extent of liver scarring. (Id. at ¶ 7). Cirrhosis typically arises in response to chronic liver disease marked by inflammation, degeneration of hepatocytes and replacement with fibrotic scar tissue. (Id.). Compensated cirrhosis means that, despite the on-going damage to the liver because of the underlying condition, the liver continues to demonstrate its ability to carry out its normal functions. (Id. at ¶ 8). The degrees of cirrhosis range from mild to moderate and severe. (Id.). Severe cirrhosis can progress to decompensated cirrhosis potentially affecting normal liver function. (Id.). The cirrhosis progression rate varies from patient to patient. (Id.).

II. HCV TREATMENT WITHIN MDOC

Under its MDOC contract, Corizon provides a defined scope of medical services to inmates in MDOC's custody. (Lovelace Decl. at ¶ 3). Protocols developed under this medical services contract (collectively, the "Missouri Policy") govern chronic HCV management and treatment in MDOC facilities. (Id. at ¶ 4).[3] The Missouri Policy is based on the Federal Bureau of Prisons ("FBOP") guidelines: (Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection: Federal Bureau of Prisons Clinical Guidance (the "FBOP Guidelines")). (Bredeman Aff. at ¶ 9; Lovelace Decl, at ¶ 7). The FBOP revised its Guidelines regarding HCV multiple times between May 2014 and August 2018. (Lovelace Decl. at ¶ 7).[4] The FBOP Guidelines contain "priority criteria" for DAA therapy "to ensure that inmates with the greatest need are identified and treated first." (FBOP Guidelines at 8). The FBOP Guidelines currently divide inmates into priority levels: "Priority Level 1: High Priority for Treatment;" "Priority Level 2: Intermediate Priority for Treatment;" and "Priority Level 3: Low Priority for Treatment." (Id.).

DAA therapy is not medically appropriate for every patient with chronic HCV. (Bredeman Aff. at ¶ 22; Lovelace Decl. at ¶ 11). Patients with acute HCV should not receive DAA therapy because their infections may self-resolve. (Bredeman Aff. at ¶ 22). As the FBOP Guidelines recognize, medical providers must consider many individualized criteria when evaluating whether DAA therapy is medically warranted and appropriate. (Id.). In addition, some patients are not

[3] The Missouri Policy includes these documents: (a) Initial HCV Chronic Care Clinic, dated December 19, 2018; (b) Follow-Up HCV Chronic Care Clinic, dated December 19, 2018; (c) Hepatitis C: Nurse Chronic Care Clinic Protocol, dated December 28, 2016; (d) Cirrhosis Pathway, dated December 19, 2018; (e) Hepatitis C Treatment Pathway, dated December 19, 2018; and (f) Considerations for Hepatitis Treatment Pathway, dated December 19, 2018. (Lovelace Decl. at ¶ 4).

[4] The current FBOP Guidelines, dated August 2018, are available at https://www.bop.gov/resources/pdfs/hcv_infection_20180906.pdf.

appropriate candidates for DAA therapy, such as (1) patients with allergies to or significant drug interactions with the prescribed medications, (2) pregnant patients, (3) patients who lack sufficient time remaining on their sentences to complete a recommended treatment course, (4) patients whose life expectancy is less than 18 months, and (5) patients who do not show a willingness to adhere to the medication regimen by abstaining from high-risk activities (such as intravenous drug use) while incarcerated. (Id.).

As the science surrounding DAA therapy has evolved, and more DAA drugs have become available, the State has provided DAA therapy to more and more inmates. For example, approximately five (5) inmates completed DAA therapy in 2015. (Lovelace Decl. at ¶ 10). In 2016, approximately fourteen (14) inmates completed DAA therapy. (Id.). Those numbers increased to approximately nineteen (19) in 2017 and approximately fifty-one (51) in 2018. (Id.). Through June 30, 2019, approximately fifty (50) inmates in MDOC custody completed DAA therapy. (Id.). An additional 150 inmates were receiving DAA therapy as of June 30, 2019. (Id.). All inmates designated Priority 1, with the exception of those who only recently received that designation, completed or were receiving DAA therapy as of June 30, 2019. (Id.).

III. THE AASLD/IDSA GUIDANCE.

The American Association for the Study of Liver Disease (the "AASLD") and the Infectious Diseases Society of America (the "IDSA") promulgate publicly-available "guidance" regarding HCV treatment (the "AASLD/IDSA Guidance").[5] Plaintiffs insist that the AASLD/IDSA Guidance represents the "current prevailing medical standard of care" for HCV. (Mot. at 10). The AASLD/IDSA Guidance itself indicates this is inaccurate, stating that it is not "intended to constitute a specific medical diagnosis, treatment, or recommendation," and that it

[5] The AASLD/IDSA Guidance is publicly available at https://www.hcvguidelines.org/.

"should not be considered complete, nor should it be relied on to suggest a course of treatment for a particular individual."[6] Moreover, the AASLD/IDSA Guidance recognizes that "in certain settings there remain factors that impact access to medications and the ability to deliver them to patients," and "[i]n these settings, clinicians may still need to decide which patients should be treated first." (Doc. No. 290-6 at 25). Finally, the AASLD/IDSA Guidance explicitly recognizes that universal DAA therapy is ***not*** currently the standard of care in prisons,[7] noting that while "antiviral therapy for chronic HCV was available in 90% of prisons . . . , few inmates actually received treatment, primarily due to antiviral therapy expense and lack of availability of trained staff." (Doc. No. 290-6 at 210). The AASLD/IDSA Guidance does not represent the current standard of care, but instead provides an aspirational recommendation. (See Declaration of Dr. Lawrence Mendel, dated August 5, 2019 ("Mendel Decl."), attached hereto as Exhibit 5, at ¶¶ 17-19). As discussed more fully below, these aspirational public health proposals cannot and should not displace the applicable constitutional standard.

STANDARD OF REVIEW

Plaintiffs seek a preliminary injunction requiring the State to implement a new policy for treating HCV infected inmates (Doc. No. 289 at 2-3). The Court cannot grant a preliminary injunction unless Plaintiffs clearly demonstrate:

(1) A substantial likelihood of success on the merits;

(2) Continuing irreparable harm if the injunction is not granted;

(3) Threatened harm to Plaintiffs that outweighs any harm that an injunction may cause the State; and

(4) The injunction will serve the public interest.

[6] http://www.hcvguidelines.org/full-report/website-policies.

[7] https://www.hcvguidelines.org/unique-populations/correctional

Id.; Dataphase, 640 F.2d at 113-14. The movant must prove **all** of the Dataphase factors by competent evidence. Watkins, Inc. v. Lewis, 346 F.3d 841, 844 (8th Cir. 2003) (emphasis added). Plaintiffs bear a particularly heavy burden because they do not seek *status quo* preservation until this Court has a chance to render a merits decision. Instead, Plaintiffs seek an injunction that effectively would provide them the permanent relief they seek. (Compare Second Am. Compl. (Doc. No. 30) at 25, seeking "preliminary and permanent injunctions directing that [the State] formulate and implement an HCV treatment policy that meets the prevailing standard of care," with Motion at 30, requesting "a preliminary injunction requiring Defendants to implement a policy that comports with the prevailing medical standard of care"). "The burden on a movant to demonstrate that a preliminary injunction is warranted is heavier when, as here, granting the preliminary injunction will in effect give the movant substantially the relief it would obtain after a trial on the merits." Calvin Klein Cosmetics Corp. v. Lenox Labs., Inc., 815 F.2d 500, 503 (8th Cir. 1987); see also Rathmann Group v. Tanenbaum, 889 F.2d 787, 790 (8th Cir. 1989) (finding that trial court's issuance of preliminary injunction was improper because it exceeded the scope of what was necessary to protect the movant until the matter could be decided on the merits). Plaintiffs' proposed injunction amounts to "a 'mandatory injunction,' meaning an injunction that changes the status quo by commanding the opposing party to perform a positive act." DeAngelis v. Ashraf, 2019 WL 2453766, at *2 (D. Conn. June 12, 2019) (denying preliminary injunction seeking DAA therapy for HCV where it amounted to a mandatory injunction). Such an injunction "should issue only upon a clear showing that the moving party is entitled to the relief requested, or where extreme or very serious damage will result from a denial of preliminary relief." Id. (citation and internal quotation marks omitted). "Moreover, in the prison context, a request for injunctive relief must always be viewed with great caution because 'judicial restraint is especially

called for in dealing with the complex and intractable problems of prison administration.'" Goff v. Harper, 60 F.3d 518, 520 (8th Cir. 1995) (quoting Rogers v. Scurr, 676 F.2d 1211, 1214 (8th Cir. 1982)). Because Plaintiffs' Motion meets no element of the four-part test, it must be denied.

ARGUMENT AND AUTHORITY

I. PLAINTIFFS LACK A SUBSTANTIAL LIKELIHOOD OF SUCCESS ON THE MERITS.

Plaintiffs cannot establish a likelihood of success for two reasons. First, they cannot establish each element of an Eighth Amendment violation.[8] Second, Plaintiffs cannot establish an exception to the State's Eleventh Amendment immunity.

A. Plaintiffs Cannot Demonstrate a Serious Medical Need For All Class Members.

The Eighth Amendment prohibits "deliberate indifference to serious medical needs of prisoners." Estelle v. Gamble, 429 U.S. 97, 104 (1976). To prevail on an Eighth Amendment claim for inadequate medical care, a plaintiff must show (1) the existence of an objectively serious medical need and (2) that the defendant knew of and disregarded that serious medical need. Coleman v. Rahija, 114 F.3d 778, 784 (8th Cir. 1997). "[T]he failure to treat a medical condition does not constitute punishment within the meaning of the Eighth Amendment unless prison officials knew that the condition created an excessive risk to the inmate's health and then failed to act on that knowledge." Long v. Nix, 86 F.3d 761, 765 (8th Cir. 1996). "[I]nmates have no constitutional right to receive a particular or requested course of treatment, and prison doctors remain free to exercise their independent medical judgment" so long as they do not cross the threshold into deliberate indifference. Dulany v. Carnahan, 132 F.3d 1234, 1239 (8th Cir. 1997). Plaintiffs cannot demonstrate that all class members have a serious medical need for immediate

[8] The Eighth Amendment applies to the states by virtue of the Fourteenth Amendment's Due Process Clause. Robinson v. California, 370 U.S. 660, 666 (1962).

DAA therapy.

The Eighth Circuit's long-standing definition of serious medical need is a condition "that has been diagnosed by a physician as requiring treatment, or one that is so obvious that even a lay person would easily recognize the necessity for a doctor's attention." Coleman, 114 F.3d at 784 (quoting Camberos v. Brandstad, 73 F.3d 174, 176 (8th Cir. 1995)). "When an inmate alleges that a delay in medical treatment constituted a constitutional deprivation, 'the objective seriousness of the deprivation should also be measured by reference to the effect of delay in treatment.'" Id. (quoting Crowley v. Hedgepeth, 109 F.3d 500, 502 (8th Cir. 1997)). The serious medical need must be one that, if left untreated, "pos[es] a substantial risk of serious harm." Farmer v. Brennan, 511 U.S. 825, 834 (1994). The burden falls upon Plaintiffs to allege and ultimately establish the existence of a serious medical need. See, e.g., Dulany, 132 F.3d at 1239. They have not done so.

Because of differences in post-infection experiences, inmates with chronic HCV do not necessarily possess a serious medical need for immediate DAA therapy. Bender v. Regier, 385 F.3d 1133, (8th Cir. 2004) ("In this case, as the district court recognized, though an HCV infection is unquestionably a serious medical problem, the Eighth Amendment issue is not whether the infection itself is a 'serious medical need,' but rather whether [plaintiff] had a serious medical need for **prompt** … treatment.") (emphasis added); Marshall v. LeBlanc, 2019 WL 2090844, at *3 (E.D. La. Mar. 6, 2019) (denying preliminary injunction where plaintiff "received ongoing medical monitoring and testing for his condition," and treating providers "determined that plaintiff's liver results are normal and that, in light of that fact antiviral treatment is not medically necessary *at this time*").[9] As Dr. Bredeman explained in an affidavit executed over two years ago, a majority

[9] White v. Secure Care Co., No. 09-13787, 2011 WL 900296, at *4 (E.D. Mich. Jan. 21, 2011) ("The case law is clear that the mere existence of a Hepatitis C infection is not necessarily a 'serious medical need' warranting treatment such that the failure to provide treatment violates the Eighth Amendment … [Plaintiff's] 'verifying medical evidence' of merely having Hepatitis C

infected with HCV will not develop liver damage, nor will they experience a risk of additional complications. (Bredeman Aff. at ¶ 6). As a result, Plaintiffs cannot establish that each class member possesses a serious medical need for immediate DAA therapy.

B. Plaintiffs Cannot Establish That the Missouri Policy Demonstrates Deliberate Indifference.

Plaintiffs must also establish the "subjective" component of an Eighth Amendment violation. In other words, Plaintiffs must prove that the State acted with "deliberate indifference." See, e.g., Farmer, 511 U.S. at 837. This subjective component requires evidence that the State possessed actual knowledge of "an excessive risk to inmate health or safety" and disregarded that risk. Id. Evidence demonstrating that the State failed "to alleviate a significant risk that [it]] should have perceived but did not, while no cause for commendation, cannot under our cases be condemned as the infliction of punishment" or sustain a deliberate indifference claim. Id. Courts summarize this component as requiring evidence of a subjectively "sufficiently culpable state of mind." Christian v. Wagner, 623 F.3d 608, 613 (8th Cir. 2010). A mere difference of opinion concerning appropriate medical care does not constitute deliberate indifference and does not violate the Eighth Amendment. Meuir v. Greene Cnty. Jail Employees, 487 F.3d 1115, 1118-19

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does not establish any 'detrimental effect of the delay in medical treatment.'); Allen v. Shawney, No. 11-10942, 2014 WL 1089618, at **11-12 (E.D. Mich. March 18, 2014) aff'd (6th Cir. June 3, 2015) (finding that plaintiff's HCV was not a sufficiently serious medical need where there was a failure to show the need for **urgent** treatment; stating that HCV "can be a serious medical condition mandating treatment" but "not all cases of hepatitis C require treatment") (emphasis added); Stevens v. Hutchinson, 2017 WL 9605115, at *7 (W.D. Mich. Dec. 6, 2017) Report and Recommendation Adopted as Modified, 2018 WL 1557251 (W.D. Mich. March 30, 2018) ("It is well-established that not all cases of Hepatitis C require treatment. HCV does not fall into the category of a medical condition providing an 'obvious' need for medical treatment.") (citations omitted); Villarreal v. Holland, 2016 WL 208310, at *8 (E.D. Kan. Jan. 15, 2016) (finding that plaintiff diagnosed with HCV failed to satisfy the objective prong of the deliberate indifference test where he failed to produce "biopsies, ultrasounds, blood tests, consultation notes, examination notes, or any other medical reports suggesting that he ha[d] suffered actual harm due to the denial of the requested drug therapy treatment").

(8th Cir. 2007). Rather, the treatment must be "so inappropriate as to evidence intentional maltreatment or a refusal to provide essential care." Dulany, 132 F.3d at 1241. Showing negligence or medical malpractice is not sufficient to state a claim for deliberate indifference. Estelle, 429 U.S. at 106. Additionally, a "prisoner must show more than negligence, more even than gross negligence, and mere disagreement with treatment decisions does not rise to the level of a constitutional violation." Estate of Rosenberg by Rosenberg v. Crandall, 56 F.3d 35, 37 (8th Cir. 1995).

"The question whether … additional diagnostic techniques or forms of treatment is indicated is a classic example of a matter for medical judgment." Estelle, 429 U.S. at 107. Where a prisoner who has received some medical attention disputes the adequacy of the treatment, federal courts must be reluctant to second guess medical judgments. Popoalii v. Correctional Med. Servs., 512 F.3d 488, 499 (8th Cir. 2008); Long v. Nix, 86 F.3d 761, 765 (8th Cir. 1996) ("[N]othing in the Eighth Amendment prevents prison doctors from exercising their independent professional judgment.") "The fact that [plaintiffs] disagree[]… and would have preferred to have been treated with antiviral therapy from the onset of [their diagnoses] does not constitute cruel and unusual punishment." Collins v. Wilkerson, 2008 WL 1844320, at *4 (S.D. Ohio Apr. 22, 2008).[10] Indeed, this case presents a claim of medical preference rather than medical necessity.

[10] See also Outlaw v. Turner, 54 Fed. Appx. 229 (7th Cir. 2002) (state prison officials' implementation of directive establishing procedures for treating HCV did not demonstrate deliberate indifference to inmate's medical needs); Black v. Alabama Dept. of Corr., 578 Fed. Appx. 794 (11th Cir. 2014) (same); Taylor v. Ortiz, 410 Fed. Appx. 76, 77 (10th Cir. 2010) ("[F]or the majority of patients, Hepatitis C causes only mild liver damage. The primary danger of Hepatitis C is the increased risk of developing liver cirrhosis or liver cancer, which generally takes decades to occur." Because the plaintiff received periodic blood labs that monitored his liver condition, the court found no Eighth Amendment violation.); Baumann v. Buttarazzi, 2008 WL 4000412, at *7 n.31 (N.D.N.Y. Aug. 22, 2008) (collecting cases showing that monitoring HCV constitutes treatment); Cowan v. Allen, 2012 U.S. Dist. LEXIS 103533, at *5-6 (N.D. Ala. July 5, 2012) ("It is clear that the decision to administer drug therapy for Hepatitis C is an extremely complicated one which involves consideration of numerous individual factors that differ from

Furthermore, Plaintiffs cannot attach any level of liability to the State under section 1983 for the actions or omissions of any other person or entity. Under section 1983, there is no *respondeat superior* or vicarious liability. Monell v. New York City Dep't of Soc. Servs., 436 U.S. 658, 694-95 (1978). Plaintiffs must identify an official policy and demonstrate that the policy inflicts actual harm. Id. So, the policy itself must be unconstitutional, i.e., demonstrate deliberate indifference to a serious medical need, and be the moving force behind the constitutional violation. See Sanders v. Sears, Roebuck & Co., 984 F.2d 972, 975-76 (8th Cir. 1993). Plaintiffs cannot show that the Missouri Policy amounts to deliberate indifference to a serious medical need. To the contrary, the Missouri Policy provides for inmates to receive DAA therapy for HCV according to their medical need.

An inmate making an Eighth Amendment claim about sophisticated injury treatment also must offer causal proof of that injury by expert testimony. Gibson v. Weber, 433 F. 3d 642, 646 (8th Cir. 2006). If an inmate's Eighth Amendment claim is based on a delay in medical treatment (e.g. a delay in receiving DAA therapy), "the inmate 'must place verifying medical evidence in the record to establish the detrimental effect of the delay in medical treatment to succeed.'" Cullor v. Baldwin, 830 F. 3d 830, 837 (8th Cir. 2016). As one United States Court of Appeals explained:

> [The plaintiff] cannot prove that the [Department] … was deliberately and culpably indifferent to a need for testing and treatment after [plaintiff] was first objectively diagnosed with the Hepatitis C virus … [Further, plaintiff] has failed to proffer verifying medical evidence of a 'detrimental effect' caused by a delay in treatment that exposes [him] to an unreasonable risk of serious harm in the future … [Plaintiff's] disagreement with the testing and treatment he has received since being diagnosed with Hepatitis C does not rise to the level of an Eighth Amendment violation.

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patient to patient … It is clear that the plaintiff has no right to insist on a particular course of treatment. . . . It seems clear that States have a legitimate interest in … avoiding unnecessary expenditures of vital resources.").

Dodson v. Wilkinson, 304 F. App'x 434, 439-40 (6th Cir. 2008).[11] Put otherwise, a delay in providing medication does not support an Eighth Amendment violation claim unless the delay caused substantial harm. See Coleman, 114 F.3d at 784. Plaintiffs cannot meet that standard.

In treating HCV in MDOC facilities, providers focus on each inmate's characteristics, exercising their medical judgment in choosing appropriate courses of action. (Bredeman Aff. at ¶ 24). In other words, medical professionals working within MDOC facilities possess the freedom to treat patients as they deem appropriate, without a broad mandate that requires a one-size-fits-all course of treatment. This approach is medically appropriate. In fact, the AASLD/IDSA Guidance, which Plaintiffs describe as "the medical standard of care" (Doc. 290 at 10), specifically states that: "[n]othing contained at HCVguidelines.org is intended to constitute a specific medical … recommendation … nor should it be relied on to suggest a course of treatment for a particular individual."[12] Instead, the AASLD/IDSA Guidance correctly acknowledges that providers should consider DAA therapy on an individualized basis. See, e.g., Buffkin v. Hooks, No. 1:18CV502, 2019 WL 1282785, at **6-7 (M.D.N.C. Mar. 20, 2019) (stating that "[t]he AASLD/IDSA Guidance … provides some evidence of a preferred public health policy but does not necessarily constitute the standard for judging deliberate indifference" and further stating that Guidance's goal

[11] See also Edmonds v. Robbins, 67 Fed. Appx. 872, 873 (6th Cir. 2003) ("The record establishes that [the doctor] saw [plaintiff] on a monthly basis . . . [and] . . . feels that at this time, [plaintiff's] condition does not warrant medication. . . . Furthermore, the medical literature . . . establishes that medication is not always required for the treatment of Hepatitis C. . . . [Plaintiff] has not established that [the doctor] is subjecting him to cruel and unusual punishment."); Hix v. Tenn. Dep't. of Corr., 196 F. App'x 350, 357 (6th Cir. 2006) (allegations that prison doctors did not prescribe the HCV treatment that prisoner desired "established nothing more than a mere difference of opinion with the doctors' diagnoses and prescribed treatment," and could not support a claim); Johnson v. Million, 60 F. App'x 548 (6th Cir. 2003) (prison medical officials were not deliberately indifferent to inmate's medical condition after he contracted HCV, where inmate was seen in prison HCV clinic every three to four months, but was not provided drug therapy because his liver enzyme levels had stayed within normal range).

[12] http://www.hcvguidelines.org/full-report/website-policies.

to eradicate HCV, while "commendable and desirable … [does] not provide a standard for evaluating deliberate indifference in the prison system."). While Plaintiffs may prefer a different policy, it does not follow that the current policy rises to an Eighth Amendment claim, particularly when every inmate in MDOC custody diagnosed with HCV is currently receiving some treatment—even if that treatment is not the medication sought.

Plaintiffs' reference to the "current prevailing standard of care" alone demonstrates a fundamental misapplication of the appropriate Eighth Amendment standard. The standard for a constitutional violation is substantially more demanding than mere deviation from the prevailing medical standard of care. Estelle, 429 U.S. at 103 ("[A] complaint that a physician has been negligent in diagnosing or treating a medical condition does not state a valid claim of medical mistreatment under the Eighth Amendment"); Jolly v. Knudsen, 205 F.3d 1094, 1096 (8th Cir. 2000) (holding that an inmate must show more than mere negligence or even gross negligence to establish a constitutional violation); Buffkin, 2019 WL 1282785, at *9 ("[P]atient treatment is often a product of resources and circumstances. In an ideal setting, all individuals with HCV could and would be treated with DAAs upon receiving a diagnosis. However, medical care in the prison setting must be adequate, not necessarily ideal, and HCV treatment in the prison system is dependent upon the availability of resources."); Marshall, 2019 WL 2090844, at *3 (even assuming AASLD/IDSA guidelines represent the "standard of care," "that simply is not determinative;" "claims of negligence of malpractice present issues of *state* law for *state* courts, not federal constitutional issues for a federal court"); Smith v. Dozier, 2018 WL 3551503, at *4 (M.D. Ga. July 24, 2018) (granting motion to dismiss and denying motion for preliminary injunction; holding that plaintiff's disagreement with provider's determination that he did not need DAA therapy did not support deliberate indifference claim). Even if the "prevailing standard of

care" equaled the Eighth Amendment standard, inmates in MDOC custody receive treatment consistent with the applicable standards for HCV treatment in inmate populations. Plaintiffs cannot establish class-wide deliberate indifference where the State continues to provide the sought-after medication for many class members.

C. Recent Court Decisions Do Not Support A Preliminary Injunction.

Plaintiffs rely on two preliminary class action decisions from outside this Circuit that are both outliers and distinguishable from this case: (1) Stafford v. Carter, No. 1:17-cv-00289-JMS-MJD, 2018 WL 4361639 (S.D. Ind. Sept. 13, 2018); and (2) Hoffer v. Jones, 290 F. Supp. 3d 1292 (N.D. Fla. 2017).

In Stafford, the trial court excluded ***all*** of the defendant's expert testimony because the remaining defendant attempted to use a settling defendant's experts without disclosing them as its own experts; the Court only considered Plaintiffs' expert evidence. Id. at **4-6. In the ***absence of contrary evidence***, the Stafford court found that the AASLD/IDSA Guidance represents the national standard of care and that no medical justification existed to support prioritizing certain inmates for DAA therapy. Id. at *20. Here, Drs. Bredeman, Lovelace, and Mendel all three dispute Plaintiffs' claims about the standard of care, and the State expects to present additional evidence on this issue at the forthcoming preliminary injunction hearing.

The Hoffer court granted a preliminary injunction, but on substantially different facts than those here. First, the court found that "Defendant's own expert … testified that an injunction is necessary for FDC to respond to this problem with the requisite alacrity." 290 F. Supp. 3d at 1303. The court also found when it issued the preliminary injunction that only thirteen (13) inmates had received DAA therapy. Id. at 1298. By contrast here, the State expects to offer expert evidence that MDOC inmates receive appropriate HCV care. (See Mendel Decl. at ¶¶ 20, 21). The number

of MDOC inmates receiving DAA therapy continues to increase. (Lovelace Decl. at ¶ 10).

Nor does the preliminary injunction represent the Hoffer court's final word about DAA therapy. Instead, the Hoffer court later issued an opinion resolving the case on cross-summary-judgment motions, entered a permanent injunction, and provided more guidance on DAA therapy. Hoffer v. Inch, 2019 WL 1747074, No. 4:17cv214-MW/CAS (N.D. Fla. Apr. 18, 2019) (appeal pending). In that opinion, currently on appeal to the Eleventh Circuit, the Hoffer court made clear that *medical* reasons could exclude inmates from DAA therapy. Id. at *14 ("If medical staff conclude that there is a *medical* reason to deny an inmate treatment because of the inmate's illicit drug use or fighting, then so be it.") (emphasis in original). The Hoffer Court also found that excluding inmates from DAA therapy when the inmate's sentence had insufficient time remaining to complete a DAA therapy course was appropriate when supported by medical judgment. See id. at **13-14. The Hoffer court summarized its findings:

> Where there was reasonable medical disagreement about a request for relief, this Court recognized that it could not order [FDOC] to change its conduct. However, where there was no medical reason for particular conduct . . . this Court properly concluded that [FDOC] needed to change course.

Id. at *19. Hoffer provides further support to conclude that much of the inmate population diagnosed with HCV does not possess a constitutional right to immediate DAA therapy.[13]

A recent Tennessee decision shows a more common-sense approach to addressing HCV in prisons. In Graham v. Parker, (No. 3:16-cv-1954) (M.D. Tenn. June 6, 2019) (attached hereto as

[13] In Abu-Jamal v. Wetzel, No. 3:16-CV-2000, 2017 WL 34700 (M.D. Pa. January 3, 2017), an action involving a single plaintiff, the trial court specifically found that there was no medical reason supporting the decision to deny the individual plaintiff DAA therapy. Abu-Jamal, 2017 WL 34700, at *11. In fact, one of the defendant doctors testified that he was unaware of any medical reason to deny DAA therapy to plaintiff. Id. at *19. Presumably, if a medical justification existed to exclude plaintiff from DAA therapy, the plaintiff would not have been entitled to any relief. Thus, this decision about this individual plaintiff does not apply broadly to all HCV-positive inmates and does not support Plaintiffs' requested injunctive relief.

Exhibit 2), the Court denied Plaintiffs' summary-judgment motion in a class action[14] seeking prospective injunctive relief. The Court set forth the genuine disputes between the plaintiffs and defendants:

> This is a lawsuit about how Tennessee evaluates and provides medical treatment to its HCV-positive prison population. But the parties differ on their understandings of both (1) the science underlying how these decisions are made (e.g., when DAA treatment is necessary and appropriate) and (2) [Tennessee Department of Corrections ("TDOC")] policies and practices guiding the [TDOC Advisory Committee on HIV and Viral Hepatitis Prevention and Treatment ("TACHH")]'s decision-making process. To illustrate these disputed factual issues, the Court need go no further than the parties' disagreement about: (1) the symptoms of HCV; (2) the progression of HCV; (3) whether DAAs are the standard of care for treatment of HCV-positive individuals in the early stages of the disease; whether [TDOC's] HCV Guidance states TDOC's 'current policy' on HCV diagnosis and treatment; (5) what criteria the TACHH utilizes in deciding whether to administer DAAs to inmates; and (6) the number of patients that have received DAAs.

Mem. Op., Graham v. Parker (No. 3:16-cv-1954, Doc. 181, at 5-6) (M.D. Tenn. filed June 6, 2019). Furthermore, in denying Plaintiffs' summary-judgment motion, the Court emphasized that: "Plaintiffs will have to show that Defendants' practices and procedures related to *all* inmates who have [hepatitis C] are unconstitutional and that Defendants' practices and procedures for all inmates with hepatitis C should be revised." Id. at 9 (emphasis in original). Plaintiffs cannot show that the management and treatment of ***all*** MDOC inmates with chronic HCV is unconstitutional. The more recent Graham case demonstrates that Stafford is an outlier and does not support

[14] The Tennessee Court previously certified the following class:

> All persons currently incarcerated in any facility under the supervision of control of the [TDOC] or persons incarcerated in a public or privately owned facility for whom the [TDOC] has ultimate responsibility for their medical care and who have at least 90 days or more remaining to serve on their sentences and are either currently diagnosed with [HCV] or are determined to have [HCV] after a screening test has been administered by the [TDOC].

Mem. Op., Graham v. Parker (No. 3:16-cv-1954, Doc. 181 at 3) (M.D. Tenn. June 6, 2019).

Plaintiffs' claims.

In a recent North Carolina decision, the trial court granted in part and denied in part Plaintiffs' Motion for Preliminary Injunction, finding that an injunction requiring correctional officials to screen and provide DAA therapy to all HCV-positive inmates regardless of fibrosis level was not appropriate or supported by the most recent medical literature. Buffkin, 2019 WL 1282785, at *12. The court found that plaintiffs failed to show that defendants' policy of providing DAA therapy to certain inmates with discretion given to treating physicians to provide care on an individualized basis was not likely to violate the Eighth Amendment such that plaintiffs were not entitled to the broad injunctive relief they sought. Id. at *10. Similarly, Plaintiffs in this case cannot show that the treatment they received is likely to constitute deliberate indifference such that they are entitled to the broad relief requested in their Motion.

Plaintiffs face insurmountable hurdles in establishing that all class members received constitutionally inadequate care. For examples of these hurdles, the Court need look no further than the named Plaintiffs themselves. Michael Postawko actually completed DAA therapy. (Deposition of Michael Postawko, dated April 23, 2019, at 155:23-156:1; 177:22-24, attached hereto as Exhibit 3). Confirming the existence of the 15% to 20% of the patients who clear their infection without further medical intervention, Michael Jamerson underwent lab testing on multiple occasions confirming the absence of any continuing or chronic infection. (Deposition of Michael Jamerson, dated April 24, 2019, at 18:10-20:5, attached hereto as Exhibit 4). No constitutional violation exists when Plaintiffs can present no plausible justification for prescribing the sought-after medication.

In sum, Eighth Circuit and nationwide prevailing law belies Plaintiffs' assertion that ***all*** inmates with HCV, without regard to the degree of liver scarring, substance abuse, or prior course

of DAA therapy, must receive DAA therapy. Plaintiffs essentially call upon the Court to override every aspect of clinical judgment afforded to physicians working within the MDOC. As a result, Plaintiffs cannot establish a likelihood of success on the merits.

D. Plaintiffs Cannot Establish any Exceptions to the State's Eleventh Amendment or Legislative Immunity.

i. The State is immune from suit under the Eleventh Amendment, and Plaintiffs cannot prove an immunity exception under Ex parte Young.

Plaintiffs cannot establish a likelihood of success on the merits because the State possesses immunity under the Eleventh Amendment, and Plaintiffs are not likely to prove an exception to the general immunity rule. Under Missouri law, "[s]overeign immunity, if not waived, bars suits against employees in their official capacity, as such suits are essentially direct claims against the state." Betts-Lucas v. Hartmann, 87 S.W.3d 310, 327 (Mo. Ct. App. W.D. 2002). The Eighth Circuit has confirmed that a state, or state actor's, Eleventh Amendment immunity applies to claims for damages, declaratory relief, and injunctive relief. Church v. Missouri, 913 F.3d 736, 747-48 (8th Cir. 2019).

With a state actor's presumptive Eleventh Amendment immunity in mind, Ex parte Young, 209 U.S. 123 (1908), provides a limited, judicially-created exception to the immunity long-afforded to state officials. Ex parte Young generally applies in situations where a state actor must be restrained from violating federal law or enforcing unconstitutional legislation. See Va. Office for Prot. & Advocacy v. Stewart, 563 U.S. 247, 255 (2011); Digital Recognition Network, Inc. v. Hutchinson, 803 F.3d 952, 957 (8th Cir. 2015) ("Enforcement of unconstitutional legislation 'is simply an illegal act upon the part of [the] state official,' and the State may not immunize officials from suit for such violations of the Constitution.") (quoting Young, 209 U.S. at 159). "The doctrine 'rests on the premise – less delicately called a 'fiction' – that when a federal court

commands a state official to do nothing more than refrain from violating federal law, he is not the State for sovereign immunity purposes.'" Id. at 747 (citing Stewart, 563 U.S. at 255).

However, the Ex parte Young exception is not boundless. In the Eighth Circuit, the Ex parte Young doctrine applies only where the complaint (1) alleges an ongoing violation of federal law[15] and (2) seeks prospective relief. Church, 913 F.3d at 748 (citing Care Comm. v. Arneson, 638 F.3d 621, 632 (8th Cir. 2011)). These rules flow from the premise that the state official must have at least "some connection to the enforcement of the challenged laws." Calzone v. Hawley, 866 F.3d 866, 869 (8th Cir. 2017) (citing Young, 209 U.S. at 157).

The Ex parte Young doctrine therefore does *not* create an avenue for litigation against state officials in their official capacities where those officials clearly lack the authority to provide the requested relief. In other words, if the state official cannot correct the purported constitutional violations, Eleventh Amendment immunity attaches and Ex parte Young does not apply. See Church, 913 F.3d at 748; see also Schallop v. New York State Dep't of Law, 20 F. Supp. 2d 384, 391 (N.D.N.Y 1998) (holding that the Ex parte Young exception "only applies in circumstances where the state official has the authority to perform the required act" and dismissing official-capacity claims against two defendants who lacked authority to reinstate a terminated plaintiff); Klein v. Univ. of Kansas Med. Ctr., 975 F. Supp. 1408, 1417 (D. Kan. 1997) (noting that, under Ex parte Young, a state official must possess the power to perform the act required in order to overcome sovereign immunity). Therefore, strict limitations exist for claims against state actors traveling under Ex Parte Young.

These limits on the Ex parte Young exception are a reflection of (1) the fundamental premise that state actors are generally immune from suit, and (2) the intricacies of States'

[15] As discussed in Section II, Plaintiffs fail to allege an ongoing federal law violation.

governmental structures. First, Ex parte Young depends upon the fundamental assumption that courts, invoking the doctrine, could actually compel the state official named as a defendant to undertake the ordered relief. Second, the government is not a monolith, and each particular entity can act only within the limits of its constitutional and/or statutory power. Within the executive branch, roles and responsibilities are delineated such that, in order to address various problems, cooperation often is required among more than one independent department or agency. By limiting the Ex parte Young exception to situations in which the state officials possess the authority to provide the requested relief, the courts honor the principle of sovereign immunity while acknowledging the practical challenges that official-capacity defendants often face.

For example, the Seventh Circuit concluded that Ex parte Young did not permit an injunction to prevent state budget cuts, because "the injunction would force the defendants, acting in their official capacities, to extract funds from the State's treasury for the ultimate benefit of the plaintiffs," and this result was "the essence of the relief sought." Council 31 of AFSCME v. Quinn, 680 F.3d 875, 884 (7th Cir. 2012). As such, relief touching upon the Missouri treasury seeking relief for the ultimate benefit of Plaintiffs does not fall within the acceptable claims available via Ex Parte Young.

Plaintiffs seek an order requiring the State to provide DAA therapy to every class member with a chronic HCV infection, with a few very limited exceptions. (Mot. at 12). It would cost MDOC approximately $90 million to do so. (Lovelace Decl. at ¶ 11). Neither MDOC nor its director possesses the authority to increase MDOC's budget by $90 million. MDOC's funding comes from General Assembly appropriations[16] Moreover, $90 million represents approximately

[16] See generally https://doc.mo.gov/director/office-director/budget-unit.

68% of the total budget for medical services to MDOC inmates. (Id.).[17] If this Court were to grant injunctive relief, it would require substantial payments from the State's treasury. These disbursements would not be ancillary to but rather would be "the essence of the relief sought." Council 31, 680 F.3d at 884. Ex parte Young does not permit such injunctive relief. Id.; Va. Office for Protection & Advocacy, 563 U.S. at 255-57.

Given the historical uses of these budgeted funds for necessary medical care, including payroll for medical staff, medications for the remaining inmate population, and other services, the State cannot comply with the proposed order without a substantial increase in MDOC's budget, and MDOC and its director lack the authority to increase MDOC's budget. This Court may not compel state officials to perform acts they lack the authority to perform. Eleventh Amendment immunity therefore bars Plaintiffs' proposed relief.

ii. Plaintiffs cannot prove that their requested injunction would not encroach on legislative immunity afforded to states' budgetary decisions.

In addition, Plaintiffs are unlikely to succeed on their claims because legislative immunity attaches to state decisions that implicate budgetary policies and priorities. Under the Missouri Constitution, "the budget process . . . begins and ends with the Governor." Mo. Health Care Ass'n v. Holden, 89 S.W.3d 504, 508 (Mo. 2002) (en banc). The General Assembly then has exclusive authority to appropriate funds from the State's treasury. Mo. Const. Art. III, § 36. In suits challenging budgetary decisions, the Missouri Supreme Court has held that Missouri's "constitution does not permit the state to spend money it does not have." Mo. Health Care Ass'n, 89 S.W.3d at 507.

[17] This number is dependent on a number of factors, including but not limited to the specific genotype of HCV and specific type of DAA therapy required for each inmate, the timing of DAA therapy, and potential changes in the inmate population.

The Supreme Court and the Eighth Circuit have consistently recognized that an executive official's budgetary decisions are integral to the legislative process and fall within the scope of absolute legislative immunity. "[A] discretionary, policymaking decision implicating the budgetary priorities of the [State] and the services the [State] provides" constitutes a legislative act. Bogan v. Scott-Harris, 523 U.S. 44, 54-55 (1998). "Whether an act is legislative turns on the nature of the act itself, rather than on the motive or intent of the official performing it." Id. at 54.

The Eighth Circuit has interpreted the Supreme Court's legislative immunity jurisprudence to hold that it is the "basis" for a suit that governs whether legislative immunity "foreclose[s] suit." Church v. Missouri, 913 F.3d 736, 752 (8th Cir. 2019) (citing Supreme Court of Virginia v. Consumers Union of U.S., Inc., 446 U.S. 719, 734 (1980)). In Church, the Eighth Circuit recognized that state government officials have immunity when granting relief would require the officials to make budgetary decisions. The plaintiffs in Church claimed that the State and certain of its agencies failed to provide constitutionally adequate legal representation to indigent criminal defendants. Church, 913 F.3d at 741. They sought "a declaratory judgment stating that their right to counsel is being violated and an order enjoining the ongoing violation of their rights and requiring Defendants to propose a remedial plan to the court." Id. at 741. The Eighth Circuit held that the Governor's authority to reduce appropriations, and withhold millions of dollars from the state public defender commission, was quintessentially legislative in character and therefore the Governor's decisions were shielded by legislative immunity.

Here, the basis for Plaintiffs' suit is MDOC's alleged failure to provide a specific therapy for HCV to inmates. This act is inextricably intertwined with the General Assembly's appropriations and the budgetary priorities and decisions that naturally accompany the appropriations process. MDOC is already providing DAA therapy to a substantial (and increasing)

number of inmates, following a prioritization process based on severity of medical condition and limited by available funding. Any injunction would also require prioritization due to financial constraints. Given the estimated cost of complying with Plaintiffs' requested relief, granting an injunction would invariably infringe upon the appropriations and budgetary process, and therefore Defendants' legislative immunity. It is the nature of the act itself—here, providing DAA therapy for HCV that would subsume a majority of the budget for medical and mental health treatment within MDOC—that invokes legislative immunity. Based on the General Assembly's appropriations decisions, MDOC must make the policy judgment of which programs and services are provided with the limited funds appropriated.

II. PLAINTIFFS HAVE NOT AND CANNOT SHOW AN IMMEDIATE AND IRREPARABLE INJURY.

A preliminary injunction is unavailable absent a showing of irreparable injury. See City of Los Angeles v. Lyons, 461 U.S. 95, 111 (1983). A showing of irreparable injury is the "*sine qua non* of injunctive relief." Frejlach v. Butler, 573 F.2d 1026, 1027 (8th Cir. 1978). An "irreparable injury" is more than merely "substantial" harm. Quaker Oats Co. v. QO Chemicals, Inc., 1995 WL 17217909, at *8 (N.D. Iowa June 15, 1995) (citing Sampson v. Murray, 415 U.S. 61, 90 (1974)). Moreover, a purported irreparable injury "must be neither remote nor speculative, but actual and imminent." Id. (quoting Tucker Anthony Realty Corp. V. Schlesinger, 888 F.2d 969, 973 (2d Cir.1989). Plaintiffs cannot show an irreparable injury.

The irreparable injury requirement is particularly important in cases involving prisons, because the PLRA imposes clear limitations on the scope and extent of injunctive relief. The PLRA states:

> Prospective relief in any civil action with respect to prison conditions shall extend no further than necessary to correct the violation of the Federal right of a particular plaintiff or plaintiffs. The court shall not grant or approve any prospective relief unless the court finds that such relief is ***narrowly drawn, extends no further than necessary to correct the violation of the***

> ***Federal right, and is the least intrusive means necessary to correct the violation of the Federal right***. The court shall give substantial weight to any adverse impact on public safety or the operation of a criminal justice system caused by the relief.

18 U.S.C. § 3626(a)(1)(A) (emphasis added). Therefore, Plaintiffs' proposed injunction is not narrowly drawn to address only an ***actual ongoing constitutional violation***. See, e.g.. Hines v. Anderson, 547 F.3d 915, 922 (8th Cir. 2008) (finding that a decree failed to meet the requirements of identical language in section 3626(b)(3) where the "type of day-to-day oversight on all aspects of medical care encompassed in the decree is broader than necessary to assure protection of this right").

Plaintiffs fail the threshold requirement of alleging a current, ongoing constitutional violation. As set forth above, HCV treatment in MDOC is rapidly evolving. Plaintiffs argue that "fewer than 10 inmates" received DAA therapy in 2016. (Mot. at 15). However, that number has steadily increased. As of June 30, 2019, fifty (50) inmates in 2019 had completed DAA therapy, and another 150 were receiving DAA therapy. (Lovelace Decl. at ¶ 10). All inmates designated Priority 1, except those who only recently received the designation, have already received DAA therapy. (Id.). The treatment MDOC inmates received in 2016 is simply not relevant to whether there exists a current, ongoing constitutional violation with respect to DAA therapy.

Moreover, Plaintiffs do not sufficiently allege imminent harm. As discussed above, many inmates will clear the virus on their own without medical intervention (like Plaintiff Jamerson), while others will not develop any acute infection symptoms. (Bredeman Aff. at ¶ 5). For other inmates, chronic HCV infection progression to some level of fibrosis remains a slow, methodical process spanning years and decades. (Id. at ¶ 6). Given these timelines, as well as the many potential outcomes, Plaintiffs cannot establish imminent class harm absent an injunction.

Plaintiffs' proposed remedy also does not meet the PLRA's "need-narrowness-intrusiveness" standard. As set forth above, DAA therapy is medically inappropriate for certain class members, including those who will clear the virus, those with insufficient time remaining on their sentences, and those with a demonstrated inability to adhere to treatment regimes or abstain from high-risk behavior. (Bredeman Aff. at ¶ 22). The remedy is not narrowly drawn because it would apply immediately to all inmates with HCV, even those who will clear the virus on their own or who will not experience worsening symptoms for many years, and therefore do not possess an immediate need for DAA therapy. Providing DAA therapy to inmates who do not need it, by definition, is not a narrowly drawn remedy. Plaintiffs' broad proposed remedy also intrudes on the decision-making process of the medical professionals who are trained to use their best judgment on how to treat HCV infected inmates. As a result, the proposed remedy fails all three elements of the PLRA standard.

Additionally, Supreme Court precedent makes clear that this Court may not become the *de facto* manager and/or administrator of the Missouri prison system. See Beard v. Banks, 548 U.S. 521, 521–22 (2006) (noting that courts owe "substantial deference to the professional judgment of prison administrators"). The Supreme Court routinely directs courts to defer to prison administrators, especially concerning matters within their discretion and expertise. In Turner v. Safley, the Supreme Court cautioned against judicial intervention in a prison system:

> A … principle identified in Martinez, however, is the recognition that 'courts are ill equipped to deal with the increasingly urgent problems of prison administration and reform.' Id., at 405, 94 S.Ct., at 1807. As the Martinez court acknowledged, 'the problems of prisons in America are complex and intractable, and, more to the point, they are not readily susceptible of resolution by decree.' Id., at 404-405, 94 S.Ct., at 1807. Running a prison is an inordinately difficult undertaking that requires expertise, planning, and the commitment of resources, all of which are peculiarly within the province of the legislative and executive branches of government. Prison administration is, moreover, a task that has been

> committed to the responsibility of those branches, and separation of powers concerns counsel a policy of judicial restraint.

482 U.S. at 84-85. The Eighth Circuit expressed a similar view in Quinn v. Nix, in which it held, "federal courts must defer to the judgment of those officials responsible for the inordinately difficult task of operating a prison." 983 F.2d 115, 118 (8th Cir. 1993) (citing Turner v. Safley, 482 U.S. 78, 84–85 (1987)). Thus, courts must avoid substituting their judgment for those of prison administrators. Bell v. Wolfish, 441 U.S. 520, 554 (1979); Spence v. Farrier, 807 F.2d 753, 756 (8th Cir. 1986) (cautioning that court should not be "too ready to exercise oversight and put aside the judgment of prison administrators"); Williams v. Hobbs, 662 F.3d 994, 1007 (8th Cir. 2011) (same); Meachum v. Fano, 427 U.S. 215, 229 (1976) ("The federal courts do not sit to supervise state prisons, the administration of which is of acute interest to the States.").

Here, Plaintiffs cannot identify, much less demonstrate, an imminent and irreparable injury that justifies extraordinary relief through the broad preliminary injunction they seek. Significantly, even if Plaintiffs established a substantial likelihood of success on the merits (which they have not done), the lack of an immediate and irreparable injury, standing alone, renders injunctive relief improper.[18] Moreover, Plaintiffs' proposed injunctive relief would violate the need-narrowness-intrusiveness standard of the PLRA. As a result, the Motion must be denied.

III. ANY PURPORTED INJURY TO PLAINTIFFS IS OUTWEIGHED BY THE HARDSHIP THE PROPOSED INJUNCTION MAY CAUSE THE STATE.

Plaintiffs fail to establish the third element of the preliminary injunction standard, i.e., that

[18] See Goff v. Harper, 60 F.3d 518, 520 (8th Cir. 1995) (citing Modern Computer Sys. v. Modern Banking Sys., 871 F.2d 734, 738 (8th Cir.1989) ("While no single factor in the balancing of the equities is determinative, the absence of a finding of irreparable injury is sufficient grounds for vacating a preliminary injunction."); Watkins Inc. v. Lewis, 346 F.3d 841, 844 (8th Cir. 2003) (same); Baker Elec. Coop., Inc. v. Chaske, 28 F.3d 1466, 1472 (8th Cir.1994) ("No single factor in itself is dispositive.... However, a party moving for a preliminary injunction is required to show the threat of irreparable harm.").

the balance of harms weighs in their favor. Indeed, the harm to the State would be substantial, especially in light of the broad scope of relief requested.

The proposed relief would cost roughly $90 million. (Lovelace Decl. at ¶ 11). As set forth above, MDOC lacks the authority to increase its own budget and instead must seek funds through the appropriations process. If forced to use budgeted funds to provide HCV treatment that is later determined to be medically unnecessary, the State would need to curtail other ***necessary*** medical services, including necessary treatment to the other inmates in MDOC's custody with different, possibly more pressing, medical needs. (Id.). Given the State's finite resources, any increased spending on DAA therapy necessarily will mean spending cuts elsewhere. These effects would likely not be reversible should the Court ultimately determine, at trial, that it granted an overly broad preliminary injunction.

The State is not suggesting that cost concerns should override medically necessary treatment. The State provides DAA therapy when medical professionals deem it medically necessary. (Lovelace Decl. at ¶ 10). As set forth above, Plaintiffs' request for DAA therapy for all inmates with HCV represents an aspirational goal, not a constitutional standard. See Buffkin, 2019 WL 1282785, at *9 ("[T]his court is concerned by: (1) the use of aspirational public health goals to establish deliberate indifference in the prison context, and (2) the limited medical resources available to a correctional institution."); Winslow v. Prison Health Servs., 406 Fed. Appx. 671, 674 (6th Cir. 2011) ("[P]risoners do not have a constitutional right to limitless medical care, free of the cost constraints under which law-abiding citizens receive treatment."). Thus, an overly broad preliminary injunction would cause hardship not only to the State but to other inmates. By contrast, in the absence of a preliminary injunction, class members will continue to receive HCV treatment, including DAA therapy for class members whose medical providers deem

such therapy medically necessary.

IV. NO PUBLIC INTEREST IS SERVED BY AFFORDING PLAINTIFFS INJUNCTIVE RELIEF.

Lastly, a preliminary injunction would not serve the public interest. Plaintiffs' interest in receiving DAA therapy is personal to them and does not implicate the public interest. Plaintiffs argue that their proposed injunction "would also indirectly benefit the public health by reducing the risk of spreading disease to other people in and out of prison." (Mot. at 29). "Deliberate indifference, however, means indifference to inmate care, not to treatment methods intended to benefit society as a whole (for example, by accomplishing the public policy aspiration of eradicating" HCV). Buffkin, 2019 WL 1282785, at *6. Thus, Plaintiffs' "public interest" argument is irrelevant to their Eighth Amendment claims.

Moreover, it is in the public interest to provide corrections officials the latitude to handle their jobs without undue court intervention. It is ***not*** the federal courts' role to set aside prison officials' decisions that a court may view as lacking wisdom or compassion. The prison systems in this country rely upon prison officials' discretion and judgment; section 1983 is not intended to allow federal courts to substitute their judgment for the exercise of that discretion. Turner v. Safley, 482 U.S. 78, 84-85 (1987); Bell v. Wolfish, 441 U.S. 520, 554 (1979); Salazar v U.T.M.B. Corr. Managed Care, 2018 WL 671362, at *2 (N.D. Tex. Jan. 5, 2018) (recommending denial of preliminary injunction), 2018 WL 638318 (accepting recommendation and findings) ("Any injunction the court issues in this instance would amount to interference with the prison officials' supervision of [plaintiff] and would thus not serve the public interest."). Thus, the Court may not consider general public health concerns in weighing the "public interest" factor. Buffkin, 2019 WL 1282785, at *6.

CONCLUSION

In sum, Plaintiffs have failed to establish any of the required elements for a preliminary

injunction. As a result, Plaintiffs' Motion must be denied.

Dated: August 5, 2019.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 5th day of August, 2019, a copy of the foregoing was electronically filed with the Clerk of the U.S. District Court for the Western District of Missouri, who will send notification to the following:

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